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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/076,074 | 02/15/2002 | Matthew C. Coffey | 16596-018001 | 8498 |
| 26181 | 7590 | 04/09/2007 | EXAMINER | |
| FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022 | | | LI, BAO Q | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |
| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | | |
| 3 MONTHS | 04/09/2007 | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/076,074 | COFFEY ET AL. | |
| | Examiner | Art Unit | |
| | Bao Qun Li | 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 17 January 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 27,28,31-51,54-57 and 59 is/are pending in the application.
 4a) Of the above claim(s) 31-34 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 27,35-43,54 and 55 is/are rejected.
 7) Claim(s) 28, 44-51, 56-57, 59 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

This is a response to the amendment filed on 01/22/07. Claims 1-26, 29-30, 52-53 and 58 have been canceled. Claims 27-28, 31-51, 54-57 and 59 are pending. Claims 31-34 were withdrawn from consideration. Claims 27-28, 35-51, 54-57 and 59 are considered before the examiner.

Claim Rejections - 35 USC § 112 1st

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action

Applicants' argument filed on Jan. 17, 2007 regarding the 112 1st paragraph issue is persuasive. The rejection of claims 43 and 51 has been withdrawn.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
2. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
3. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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4. Claims 27, 36-39, 41 and 55 are still rejected over claim 27 of Lee et al. (US Patent No. 6,136,307A) in view of disclosure of Smith (Exp. Opin. Invest. Drugs, 2000, Vol. 9, No. 2, pages 311-327)

5. Claims 27, 36-39, 41 and 55 are still rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 28 of U.S. Patent No. 6,565,831B1) in view of disclosure of Smith (Exp. Opin. Invest. Drugs, 2000, Vol. 9, No. 2, pages 311-327).

6. Applicants traverse the rejection and submit that none of these documents even teach or suggest a subject having a ras-activated neoplasm capable of developing drug resistant to a chemotherapeutic agent as cited in claims 27-28. Moreover, none of the documents teaches or suggests cells that are refractory to a chemotherapeutic agent, let along step of determining in a subject if the ras-activated neoplasm is refractory to a chemotherapeutic agent.

7. Applicants' argument has been respectfully considered; however, it is not found persuasive. Because the active step for determining if the ras-activated neoplasm is refractory to a chemotherapeutic agent is not cited as an active step in claim 27. Applicants are reminded that the citation of "capability of" in claim 27 is merely a statement of a latent characteristic of said neoplasm, no patentable weight is considered as an active step.

8. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is well known in the art that any neoplasm is intended to develop resistance towards any chemotherapy. Smith et al clear teach that the combination therapy of an oncolytic virus with a chemotherapeutic agent produces a synergistic effect. An ordinary skilled in the art would have obviously selected to use such combinatory therapy to produce the more significant anti-tumor effect than use any of these treatments alone.

9. To this context, the rejections over both patents are therefore, maintained.

Claim Rejections - 35 USC § 102

10. Claims 27, 36-39, 41, 55 are still rejected under 35 U.S.C. 102(a) as being anticipated by Lee et al. (A) (US Patent No. 6,136,307A) or Lee et al. (B) (WO 00/50051A2).

11. Applicants traverse the rejection and submit that neither the '307 patent nor the '051" teaches or suggests the development of drug resistant.

12. Applicants' argument has been respectfully considered; however, it is not found persuasive. Because claims 27, 53 and 57 are directed to a method for administering reovirus co-currently or prior to the administration of the chemotherapeutic agent, the limitation of a subject capable of developing drug resistance is not considered as an active step of the claimed method. Moreover, applicants also admitted in the previous response that the process of developing a drug resistant could inherently exist during the treatment via co-administering the reovirus and chemotherapeutic agent together. To this context, there is not extra step for selecting different population of the patient who receiving the reovirus treatment. The rejection is therefore, maintained.

Claim Rejections - 35 USC § 103

13. Claims 27, 35-42, 54, 55, 56, 57 and 59 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US Patent No. 6,136,307A) or Lee et al. (B) (WO 00/50051A2) or over Mercer University (Mercer University Home page 1996, pp. 1-2) in view of Smith (Exp. Opin. Invest. Drugs, 2000, Vol. 9, No. 2, pages 311-327).

14. Applicants traverse the rejection and submit that neither the '307 patent nor the '051" teaches or suggests the development of drug resistant.

15. Applicants' argument has been respectfully considered; however, it is not found persuasive. Because claims 27, and 57 are directed to a method for administering reovirus co-currently or prior to the administration of the chemotherapeutic agent, the limitation of a subject capable of developing drug resistance is not considered as an active step of the claimed method. Moreover, applicants also admitted in the previous response that the process of developing a drug resistant could inherently exist during the treatment via co-administering the reovirus and chemotherapeutic agent together. To this context, there is not extra step for selecting different population of the patient receiving the reovirus treatment.

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16. Because Smith et al. clearly teach that treatment of cancer with reovirus in combination with a chemotherapeutic agent produces a synergistic effect, it would have been obvious for a person with ordinary skill in the art to be motivated using less dosage of therapeutic agent in combination of the enclitic reovirus to treat ras-mediated neoplasm with much better anti-tumor effect since reovirus is particularly suitable for oncolyzing the ras-mediated neoplastic cell and combination of reovirus with a chemotherapeutic agent produces a synergistic effect. The claimed invention is *prima facie* obvious absence unexpected results.

Conclusion

No claims are allowed.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bao Qun Li

March 29, 2007

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